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# TRANSMITTAL FORM

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Total Number of Pages in This Submission **6**

Application Number	09/710,058
Filing Date	November 10, 2000
First Named Inventor	ANDERSON, DAVID
Group Art Unit	1639
Examiner Name	Liu, Sue Xu
Attorney Docket Number	RIGL-011

## ENCLOSURES (check all that apply)

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Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

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Signature	
Date	September 17, 2007

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<b>REPLY BRIEF</b>  Mail Stop Appeal Brief-Patents Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	RIGL-011
	Confirmation No.	4112
	First Named Inventor	ANDERSON, DAVID
	Application Number	09/710,058
	Filing Date	November 10, 2000
	Group Art Unit	1639
	Examiner Name	Sue Liu
	Title: <i>"METHODS AND COMPOSITIONS COMPRISING RENILLA GFP"</i>	

Sir:

This Reply Brief is filed in support of Appellants' appeal of the rejections set forth in the Office Action dated October 13, 2006, and in response to the Examiner's Answer dated July 16, 2007.

The Commissioner is hereby authorized to charge deposit account number 50-0815 to cover any fee required for filing this brief.

### **REPLY BRIEF**

In this Reply Brief, the Appellants: a) recast their arguments within the framework of *KSR* (*KSR International v. Teleflex Inc.*, 127 S. Ct. 1727; 82 U.S.P.Q.2D (BNA) 1385, Supreme Court 2007), which was published after the Appeal Brief was filed; and b) address a specific issue raised in the Examiner's Answer. The Appellants believe that all arguments presented in the prior Appeal Brief still apply with equal force. However, solely in the interest of brevity and for the convenience of the Board those arguments are not reiterated herein. This Reply Brief is *supplemental* to the earlier filed Appeal Brief.

#### *KSR requires that obvious inventions require predictable success*

The “predicted success” of a combination of elements is an important factor in determining obviousness. This principle is illustrated in *three* Supreme Court<sup>1</sup> cases decided prior to *KSR*, and is a recurring theme of *KSR*. For example, in *KSR* the Supreme Court stated that in order for a combination of elements to be patentable “the combination must do more than yield a predictable result”.<sup>2</sup> Likewise, the corollary principle, namely that “The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results”<sup>3</sup> is also discussed. The Supreme Court in *KSR* also stated that that “a court *must* ask whether the improvement is more than the predictable use of prior art elements according to their established functions”.<sup>4</sup>

Thus, according to the Supreme Court, an analysis of the “predictable success” of a combination of known elements may be used to separate patentable combinations (e.g., a battery that contains water, in the case of *United States v. Adams, supra*) from those that are unpatentable (e.g., an adjustable pedal having a fixed pivot point and a sensor, in the case of *KSR, supra*).

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<sup>1</sup> *United States v. Adams*, 383 U.S. 39, 40 (1966); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.C. 57, 60-62 (1969) and *Sakraida v. AG Pro, Inc.*, 425 U.C. 273, 282 (1976).

<sup>2</sup> *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007).

<sup>3</sup> *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007).

<sup>4</sup> *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727, 1740 (2007); emphasis added.

In the instant case, the Appellants acknowledge that the claims recite a combination of known elements, namely a retroviral vector and a polynucleotide encoding wild type *Renilla* GFP. The superior spectral properties of wild type *Renilla* GFP were also known at the time of filing of the instant application.

However, the question in this case is not a question of whether all of the elements are known or whether there was some reason why one of skill in the art would have a reason to express wild type *Renilla* GFP using a retroviral vector. Rather, the question here is one of whether one of skill in the art could have predicted that the combination would have worked. Using the language of the Supreme Court in *KSR*,<sup>5</sup> would there have been a “predictable” or “anticipated” success?

In the instant case and as will be discussed in greater detail below, the art in which the claimed subject matter belongs (i.e., art from the same field as that cited to reject the claims) indicates that retroviral vectors encoding wild type GFPs are inoperative<sup>6</sup>. In view of this, the Appellants submit that the claimed subject matter would *not* be predicted to be a success. Thus, the Appellants believe that the instant claims fail the Supreme Court’s “predictable success” test, and this rejection should be reversed.

*The Examiner should give full weight to the Appellants’ supporting references*

The Examiner makes no new arguments in the Examiner’s Answer. Rather, the Examiner re-emphasizes the idea that the Appellants’ supporting references<sup>7</sup> – which collectively indicate that the practitioners in the GFP arts at the time of filing were experiencing tremendous problems in expressing wild type GFPs using a retroviral vector – are not relevant because they relate to expression of *Aequoria* GFP, rather than *Renilla* GFP.

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<sup>5</sup> *KSR International v. Teleflex Inc.*, 127 S. Ct. 1727, 1742 (2007).

<sup>6</sup> See, e.g., *Aran, Hanazono, Levy, Cheng and Anderson*; i.e., the “supporting references”, all of which unequivocally state that retroviral vectors encoding wild-type *Aequoria* GFPs do not work. Each of these references is discussed in more detail in the Appeal Brief. The Appellants believe that the supporting references represent fair evidence that practitioners in the GFP arts at the time of filing were experiencing tremendous problems in expressing wild type GFPs using a retroviral vector.

The Examiner's arguments are flawed, however, because the supporting references are from precisely the same field – the field of *Aequoria* GFP - as the references that are cited to reject the claims<sup>7</sup>.

Giving full weight to references relating to *Aequoria* GFP to support a rejection of claims directed to a *Renilla* GFP, while, at the same time, ignoring the teachings of those references that undermine the Examiner's position is inconsistent. Either the teachings of these references should be given full weight in supporting the Appellants' arguments, or the rejection should be withdrawn as being based on references that are not relevant to the claimed subject matter. The references must either be relevant for patentability of the claimed invention or *not* be relevant. Either way, the rejections should be withdrawn.

In this respect, the Appellants believe that the Examiner has erred in not giving full weight to the teachings of the supporting references. If the teachings of the supporting references are given full weight (which they should because they are from the same field as the references used to reject the claims), then it would be clear that practitioners were experiencing tremendous problems in expressing wild type GFPs using retroviral vectors.

Given full weight, the supporting references support the argument that it was known at the time of filing that wild type GFPs could not be expressed using a retroviral vector. Thus, the claimed retroviral vector would be patentable following application of KSR's "predictable success" test, and this rejection should be reversed.

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<sup>7</sup> *Aran, Anderson, Bierhuizen and Zolutukhin* describe to the expression of non-wild type *Aequoria* GFPs using retroviral vectors and are cited in support of the rejections. The Appellants supporting references - *Aran, Anderson, Hanazono, Levy and Cheng* also described the expression of non-wild type *Aequoria* GFPs using retroviral vectors, and report the failure of retroviral vectors expressing wild-type *Aequoria* GFP. *Aran* and *Anderson* are cited by the Examiner to support the rejection, and cited by the Appellants to support their arguments for patentability.

The Appellants believe that this rejection is analogous to one in which a claim to a drug that cures a disease is rejected as obvious over drugs of similar structure that do not show any effect. Because the structurally similar drugs failed, the claimed drug also would be predicted to fail. Thus, the claimed drug would fail *KSR*'s "predictable success" test, making the claimed drug patentable. The U.S. patent system should welcome this type of innovation, rather than reject it.

Reversal of this rejection is requested.

In view of the foregoing discussion and the earlier filed Appeal Brief, the Appellants respectfully request that all of the rejections be reversed, and that the application be remanded to the Examiner with instructions to issue a Notice of Allowance.

Respectfully submitted,

Date: September 17, 2007

By: 

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